

### **REMARKS**

Claims 1 – 22 are pending in the application. Claims 3, 8 and 12 have been cancelled. Claims 1, 2, 4, 5, 7, 11, 13, 14 and 20 have been amended. New claims 23 - 26 have been added and are supported by claims 1-2 and 4-5. No new matter has been added by virtue of the claims and amendments, support being found throughout the specification and the claims as originally filed.

Any cancellation of the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

### **Objections to the Specification**

The Examiner has objected to the abstract and reminds Applicant of the proper language and format for an abstract. (Office Action, p.2).

Applicants have amended the abstract using the proper language and format. Accordingly, Applicants respectfully request that the objection be withdrawn.

### **Claim Objections**

The Examiner has objected to claims 1 – 8 “because ‘nucleotide sequence’ lacks an article.” (Office Action, p.2). Applicants have amended the claims to recite an article before “nucleotide sequence” and respectfully request that the objection be withdrawn.

The Examiner has objected to claims 11 – 13. The Examiner argues that the phrase “protective response” is not an art recognized phrase. (Office Action, p.3). “Protective response” has been defined in the specification on page 26, line 16, where “the type of ‘protective response’ in the above description is not limited in any way, and encompasses production of phytoalexin, expression of PR (Pathogenesis-Related) protein, production of reactive oxygen species, formation of papilla, and lignification.” Applicants teach in reference 13, for example, that phytoalexins are a defense against microbial infection. Accordingly,

Applicants have amended the language of the claims to recite “defense response.” Applicants respectfully request that the objection be withdrawn.

The Examiner has objected to claim 13 and alleges that “communication pathway” is not an art recognized pathway. Applicants have amended the claims to recite “signaling pathway.” “Communication pathway” and “signaling pathway” are used interchangeably in the specification. For example, at page 25, line 31 Applicants teach that “any gene that activates a *communication pathway* controlling protective response of the plant may be used as transgene. Exemplary genes of this type are MEK genes which activate SIPK (salicylic acid-induced protein kinase), a mitogen-activated protein (MAP) kinase, or WIPK (Wound-Induced Protein Kinase).” (emphasis added). Protein kinase signaling pathways are well known to one of skill in the art. Accordingly, Applicants respectfully request that the objection be withdrawn.

The Examiner has objected to claim 14. The Examiner indicates that “ ‘SIPK’ and ‘WIPK’ should be spelled out.” (Office Action, p.3). Applicants have amended the claims and respectfully request that the rejection be withdrawn.

The Examiner has objected to claim 20. The Examiner indicates that “ ‘affording’ pathogen resistance is not an art recognized phrase.” Applicants have amended the term “affording” to “inducing.” Support for the term inducing is found in the specification at page 14, line 11, where “ ‘Pathogen-responsive promoter’ in the present invention means a promoter that is responsive to (induced by) pathogen infection.” Claim 20 refers to a method for affording or inducing pathogen resistance to a host plant, comprising the step of transforming the host plant with a DNA construct comprising a pathogen-responsive promoter. Accordingly, Applicants respectfully request that the objection be withdrawn.

## **Claim Rejections**

### **35 U.S.C. §112, second paragraph**

Claim 12 was rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner argues that “(c)laim 12 is confusing in the recitation of ‘a DNA cooperatively constituting with the DNA a pathogen responsive promoter’

is not defined in the specification and not recognized in the art (and) (t)herefore the metes and bounds of the claim is unclear.” (Office Action, p.3). Applicants respectfully disagree.

Without acquiescing to the validity of the Examiner’s argument, and solely in the interest of advancing prosecution, Applicants have cancelled claim 12. Accordingly, Applicants respectfully request that the rejection be withdrawn.

### **35 U.S.C. §112, first paragraph**

#### **Enablement**

Claims 1 - 22 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner alleges that the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. (Office Action, p.4). Applicants respectfully traverse the rejection.

The Examiner argues that “the specification, while being enabling for an isolated pathogen responsive promoter comprising SEQ ID NO:1 or 2 and a method of transforming a plant with a DNA construct comprising said promoter, does not reasonably provide enablement for a pathogen responsive promoter comprising SEQ ID NO: 22 or SEQ ID NO: 1 or 2 with one or more nucleotide deletion, insertions or additions; a DNA with 10 or more contiguous bases of SEQ ID NO: 23, or a DNA that hybridizes said promoter under a stringent conditions, and a method of transforming a plant with DNA construct comprising said promoter.” (Office Action, p.4).

The claims, as amended, are directed to a pathogen-responsive promoter, comprising a DNA comprising the nucleotide sequence shown in SEQ ID NO:1 or SEQ ID NO:2 and functioning as a pathogen-responsive promoter in plant cell. The claims are also directed to a pathogen-responsive promoter functioning as pathogen-responsive promoter in plant cell and comprising a DNA comprising the nucleotide sequence shown in SEQ ID NO: 22 or SEQ ID NO: 23.

The MPEP states that the determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination.

Rather, it is a conclusion reached by weighing a combination of factual considerations: the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples, and the quantity of experimentation necessary. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. Accordingly, the Examiner has considered the following factors in his rejection:

*Nature of the invention and the breadth of the claims*

According to the MPEP at 2164. 05(a), “whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. The initial inquiry is into the nature of the invention, i.e., the subject matter to which the claimed invention pertains. The nature of the invention becomes the backdrop to determine the state of the art and the level of skill possessed by one skilled in the art.”

As to the breadth of the claims, the Examiner alleges that “(t)he claims are broadly drawn to a pathogen responsive promoter comprising the nucleotide sequence SEQ ID NO: 1, 2, 22 or 23 or a nucleotide sequence thereof with one or more nucleotide deletions, substitutions or additions, or a nucleotide sequence that hybridizes thereto under stringent conditions and functions as a pathogen responsive promoter; a DNA construct, a vector, a plant comprising said promoter and a method of producing transgenic plant with said promoter operably linked to a gene.” (Office Action, p.4). The Examiner argues that “the specification, however, does not provide enablement for the broad scope of the claims.” (Office Action, page 5). Applicants disagree.

While in no way acquiescing to the validity of the Examiner’s rejection, Applicants have amended the claims to recite that the pathogen responsive promoter comprises SEQ ID NO:22 or 23 or SEQ ID NO:1 or 2. Accordingly, Applicants argue that the breadth of the claims is enabled as written.

*Working Examples and Teachings in the Specification*

According to the MPEP at 2164.02, “compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed.” Moreover, “an applicant need not have actually reduced the invention to practice prior to filing. *In Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987). The Court held that “the mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it.” 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)). “The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).”

The Examiner points out on page 5 of the Office Action that “(t)he specification does not teach deletion analysis other than those shown on Figure 30 which shows regions the promoter region from position 1287 to 1337 of SEQ ID: 1 is essential pathogen responsive activity.” The Examiner argues that “The specification does not disclose pathogen responsive promoters other than SEQ ID NO: 1 and 2, each comprising SEQ ID NO: 23 (and) the specification does not teach that the deletion, substitutions or addition of any one or more nucleotides in SEQ ID NO: 1, 2 or 22 will retain the desired pathogen response activity.” (Office Action, p.5). Applicants respectfully disagree.

First, Applicants point out that the claims have been amended to recite that the pathogen responsive promoter comprises SEQ ID NO: 22 or 23 or SEQ ID NO: 1 or 2, and the replacement, addition, insertion or deletion of one or more nucleotides has been deleted. Second, there is ample support in the specification that SEQ ID NO: 22 functions as a pathogen responsive promoter and that SEQ ID NO: 23 is highly useful for construction of a pathogen-responsive promoter, and that the region can be used in the flexible design and construction of a DNA construct incorporating the pathogen-responsive promoter. For example, Applicants direct the Examiner to the description on page 20, lines 20 – 33, Examples 9 and 10 (page 56 line 34 to page 57 line 31. page 57 lines 7-12 and lines 27-31 in particular), and Figure 29.

Accordingly, the pathogen responsive promoters are clearly taught in the present specification to enable the invention as claimed.

*The Predictability or Unpredictability of the Art*

The Examiner cites the Forgoux-Nicol et al. reference (1999, Plant Molecular Biology 40: 857 – 872) that teaches the identification of a 674 bp fragment using a 497 bp probe, where “the probe and (the) identified DNA fragment exhibited a number of sequence differences comprising a 99 bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches.” (Office Action, p.5 – 6). The Examiner uses the Forgoux-Nicol reference to argue that in the present case “the majority of DNA sequences that hybridizes to SEQ ID NO: 1, 2, 22 or to a DNA comprising SEQ ID NO: 23 or 10 contiguous bases of thereof are not expected to show pathogen responsive promoter activity.” (Office Action, p.6).

While in no way acquiescing to the validity of the Examiner’s rejection, Applicants have amended the claims to delete the hybridizing language and to delete the a DNA comprising SEQ ID NO:23 or 10 contiguous bases thereof.

Taken together, the teachings of the specification and knowledge of one of skill in the art enables one of skill in the art to practice the full scope of the claimed invention without having to resort to undue experimentation. Applicants accordingly request that the rejection be reconsidered and withdrawn.

Applicants respectfully request withdrawal of the rejection and allowance of the claims.

**Written Description**

Claims 1 - 22 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. (Office Action, p.6 - 7). Applicants respectfully traverse the rejection.

The Examiner argues that “the claims are broadly drawn to a genus of pathogen responsive promoter sequences comprising multiple of nucleotide deletions, substitutions, and additions relative to SEQ ID NO:1, 2 or 22; sequences that hybridize to the disclosed promoter

sequences under any stringency conditions, and DNA sequences comprising SEQ ID NO: 23 or sequences thereof with a fragment or 10 continuous bases (and) (i)n contrast the specification describes SEQ ID NO:1, 2 and 22 and a method of using said promoter sequences to induce pathogen resistance in transgenic plants.” (Office Action, p.7).

The claims were set forth above. Applicants point out that the claims have been amended to recite that the pathogen responsive promoter comprises SEQ ID NO:22 or 23 or SEQ ID NO: 1 or 2, and the replacement, addition, insertion or deletion of one or more nucleotides has been deleted.

The specification clearly describes the composition and structure of SEQ ID NO:23 that is sufficient to induce pathogen responsive activity, as pointed out by the Examiner on page 7 of the Office Action, and that SEQ ID NO: 22 functions as a pathogen responsive promoter. This is shown in the specification at Example 9 (page 56, line 34), where SEQ ID NO:22 and SEQ ID NO:23 were shown to induce GUS activity:

<Example 9> Response to INF1 by PVS3 Promoter Deletion  
Clone Introduced by Agroinfiltration

INF1, *P. infestans*-derived elicitor protein, is an effective elicitor for *Benthamiana* (Reference 63). Binary vectors containing GUS gene including introns linked in-frame downstream of PVS3 promoter were introduced by Agroinfiltration into *Benthamiana* leaves to examine INF1-induced GUS activity (Fig. 27). When binary vectors pPVS3-1 containing full length PVS3 promoter inserted were introduced, a significant increase of GUS activity was observed compared to water treatment (Fig. 28). In order to examine cis-sequence of PVS3 promoter response to INF1, deletion clones were produced to construct binary vectors and examine GUS activity. As a result, deletion up to -1,337 (pPVS3-2 : SEQ ID NO: 22) retained INF1 responsiveness, whereas deletion up to -1,287 (pPVS3-3) greatly reduced GUS activity induced by INF1. This result indicates that cis-sequence of PVS3 promoter is involved in 50 bp (SEQ ID NO: 23) between pPVS3-2 and pPVS3-3 (Fig. 29).

In Example 10, Applicants examine induction of PVS3 promoter by StMEK1<sup>DD</sup> and show that the 50 bp (SEQ ID NO:23) between pPVS3-2 and pPVS3-3 is involved in cis-sequence responsive to StMEK1<sup>DD</sup>.

Accordingly, the specification clearly describes SEQ ID NO:1, 2, 22 and 23 to distinguish the pathogen resistant promoter of the present invention from other pathogen resistant promoters such that a skilled artisan would find sufficient written description of the instantly claimed promoters.

Applicants respectfully request that the rejection be withdrawn.

### **Claim Rejections 35 U.S.C. §102 (b)**

Claims 1 - 6, 8 - 13 and 16 - 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,723,760 to Strittmatter et al., (the '760 reference herein). (Office Action, p.9). Applicants respectfully traverse the rejection.

The present claims pathogen responsive promoters comprising SEQ ID NO:22 or 23 or SEQ ID NO: 1 or 2. In the present claims, the replacement, addition, insertion or deletion of one or more nucleotides of SEQ ID NO:22 or 23 or SEQ ID NO: 1 or 2, and sequences that hybridize thereto, has been deleted.

To anticipate a claim, each and every element of the claim must be found in a single reference. This is discussed in the Manual of Patent Examining Procedure § 2131:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The '760 reference does not teach or suggest all the limitations of the instant claims. In particular, the '760 reference does not teach or suggest a pathogen-responsive promoter,



comprising a DNA comprising the nucleotide sequence shown in SEQ ID NO:1 or SEQ ID NO:2 or SEQ ID NO:22 or 23.

The '760 reference is directed to fungus responsive chimeric genes. As pointed out by the Examiner, the '760 reference teaches a "pathogen responsive promoter from potato in a vector or DNA construct comprising said promoter operably linked to a foreign gene that confers pathogen resistance in a plant, and a method of protecting plants...the method comprising transforming the plant with said vector." (Office Action, p.9). The Examiner argues that "(g)iven that the breath of the claims encompassing pathogen responsive promoter sequences with multiple modifications in SEQ ID NO:1, 2, 22 or 23 and sequences that hybridize thereto...the claimed promoter is indistinguishable from the prior art." (Office Action, p.9 – 10).

Nowhere does the '760 reference teach or suggest the present claims. In fact, the gene, PRP1 that is taught by the '760 reference encodes glutathione S-transferase (GST) which is not MAP kinase-dependent (see Eur. J. Biochem. 226, 619-626 provided herein), whereas PVS3, from which the present promoters are derived, is salicylic acid-induced protein kinase (SIPK) or wound-induced protein kinasae (WIPK) inducible. Clearly, the '760 reference does not apply to the present invention.

Applicants respectfully request that the rejection be withdrawn.

### **CONCLUSION**

For the reasons provided, Applicant submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105.

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Respectfully submitted,

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